# Complete Summary

## **GUIDELINE TITLE**

Chronic obstructive pulmonary disease.

# BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Chronic obstructive pulmonary disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Dec. 67 p. [113 references]

# COMPLETE SUMMARY CONTENT

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS **CONTRAINDICATIONS** QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES** 

# **SCOPE**

## DISEASE/CONDITION(S)

Chronic obstructive pulmonary disease (COPD)

IDENTIFYING INFORMATION AND AVAILABILITY

# **GUIDELINE CATEGORY**

Diagnosis Evaluation Management **Treatment** 

# CLINICAL SPECIALTY

Family Practice Internal Medicine Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Respiratory Care Practitioners

# GUIDELINE OBJECTIVE(S)

- To increase the use of spirometry in the diagnosis of patients with chronic obstructive pulmonary disease (COPD)
- To increase to 100% the number of patients with COPD who receive information on the options for tobacco cessation and information on the risks of continued smoking
- To reduce COPD exacerbation requiring Emergency Department (ED) evaluation or hospital admission
- To increase the appropriate use of pharmacotherapy prescribed for patients with COPD
- To increase patients' education and management skills with COPD
- To increase to 100% the number of patients with COPD presenting with an acute exacerbation that have an oximetric evaluation

## TARGET POPULATION

Patients with symptoms of stable chronic obstructive pulmonary disease (COPD) as well as acute exacerbation of COPD

#### INTERVENTIONS AND PRACTICES CONSIDERED

# Stable Chronic Obstructive Pulmonary Disease

# Evaluation/Diagnosis

- 1. Assessment of symptoms and/or risk factors (including tobacco use) for chronic obstructive pulmonary disease (COPD)
- 2. Medical history
- 3. Physical examination
- 4. Spirometry (pre-and post-bronchodilator)
- 5. Chest radiograph
- 6. Establish severity of COPD

# Management/Treatment of Stable COPD

- 1. Step Care Primary pharmacologic approach
  - Inhaled short-acting bronchodilator alone
  - Short-acting bronchodilator plus scheduled dosing of albuterol (Proventil®, Ventolin®) or albuterol plus ipratropium (Combivent®) or

formoterol (Foradil®) or ipratropium (Atrovent®) or salmeterol (Serevent®) or levalbuterol

- Adjunctive oral corticosteroid (prednisone)
- Inhaled corticosteroids (beclomethasone, budesonide, flunisolide, fluticasone, triamcinolone acetonide)
- Theophylline as adjunctive therapy with inhaled bronchodilators
- 2. Other pharmacologic treatment
  - Immunization with influenza and pneumococcal vaccine
  - Mucolytics
  - Antiviral agents (amantadine [Symmetrel®]), rimantidine
     [Flumadine®], zanamivir [Relenza®], oseltamivir [Tamiflu®])
  - Oral beta agonists

Note: The following treatments are discussed but not recommended: regular use of antitussives, leukotriene modifiers, routine use of antibiotics

- 3. Non-pharmacologic treatment: exercise, patient education
- 4. Assessment for and treatment of (as indicated) hypoxemia and hypercapnia: Arterial blood gas (ABG) measurement, pulse oximetry, oxygen therapy
- 5. Follow-up visits, education, and referral to pulmonary specialist and/or pulmonary rehabilitation as appropriate
- 6. Discussion with patients regarding advanced health care directives

## **Exacerbation of COPD**

# Evaluation/Diagnosis

- 1. Assessment of symptoms of COPD exacerbation
- 2. Medical history
- 3. Physical examination
- 4. Chest radiograph
- 5. Laboratory tests including ABG, theophylline level, and white blood cell count

Note: In patients with COPD exacerbation, there is not a good relationship with spirometry. For that reason, O2 saturation should be monitored. Additional laboratory testing, electrocardiography, and echocardiography were discussed but not recommended.

## Treatment

- 1. Bronchodilators such as albuterol, albuterol plus ipratropium bromide, levalbuterol (Xopenex®)
- 2. Steroids (inhaled and oral)
- 3. Antibiotics (first-line agents such as amoxicillin, trimethoprim/sulfamethoxazole, doxycycline, erythromycin or second line antibiotics such as second-generation cephalosporins, azithromycin, clarithromycin, and amoxicillin/clavulanate)
- 4. Oxygen delivery
- 5. Follow-up
- 6. Hospital admission (if no improvement)

#### MAJOR OUTCOMES CONSIDERED

- Outcomes of treatment (e.g., symptom relief, exercise tolerance, frequency of exacerbations, long-term costs, forced expiratory volume in 1 second (FEV<sub>1</sub>) measures, quality of life)
- Morbidity and mortality related to chronic obstructive pulmonary disease (COPD)
- Adverse effects of treatment

## METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

2001 Version of Guideline

Searches of the medical literature on MEDLINE have been conducted by staff of the Arneson Library at Methodist Hospital in St. Louis Park, Minnesota. An initial comprehensive search was conducted in November 1999. The search focused on randomized and/or controlled trials. In addition, the following key words and filters were used when conducting the first search: diagnosis, treatment and management, chronic bronchitis, emphysema, chronic obstructive lung disease, and asthmatic bronchitis.

- The search was limited to: ages 55 and older.
- The search was sorted by: smoking status (if available).
- The search included: English-only reviews, meta-analyses, clinical trials, and evidence-based practice parameters/guidelines published from 1994 -April 2001.

Subsequent targeted searches of the literature have been conducted using the same time frame and article types as the original search. Individual searches on the following keywords have been conducted and distributed to work group members researching related areas:

- Authors: T. Petty, M. King
- DNAse and chronic obstructive pulmonary disease (COPD)
- Dry powder inhalers (rotahaler, turbuhaler, etc) and COPD
- Nebulizers and COPD
- Patient education and COPD
- Use of quaifenesin (quaiacol glyceryl ether)
- Spacers and COPD
- Spirometry
- Corticosteroids and COPD

# 2003 Version of Guideline

Searches of the medical literature on MEDLINE have been conducted by staff of the Arneson Library at Methodist Hospital in St. Louis Park, Minnesota. The search focused on randomized and/or controlled trials. In addition, the following key words and filters were used when conducting the first search.

Keywords included: diagnosis, treatment and management, chronic bronchitis, emphysema, chronic obstructive lung disease, and asthmatic bronchitis.

The search was limited to: ages 55 and older.

The search was sorted by: smoking status (if available).

The search included: English-only reviews, meta-analyses, clinical trials, and evidence-based practice parameters/guidelines published from September 2002-October 2003.

Subsequent targeted searches of the literature have been conducted using the same time frame and article types as the original search. Individual searches on the following keywords have been conducted and distributed to work group members researching related areas:

- Dry powder inhalers (rotahaler, turbuhaler, etc) and COPD
- Nebulizers and COPD
- Patient education and COPD
- Use of guaifenesin (guaicol glyceryl ether)
- Spacers and COPD
- Spirometry
- Corticosteroids and COPD
- Levalbuterol and COPD

# NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

# RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

## Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with

negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

Randomized, controlled trial

Class B:

Cohort study

## Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- · Population-based descriptive study

## Class D:

- Cross-sectional study
- Case series
- Case report
- B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

#### Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

#### Class R:

- Consensus statement
- Consensus report
- Narrative review

#### Class X:

Medical opinion

# METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

# DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

# METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

# RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing Internal Peer Review

# DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eightweek period of "Critical Review".

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1-2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Respiratory Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

# Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Respiratory Steering Committee reviews the revised guideline and approves it for implementation.

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

The recommendations for the diagnosis and management of stable chronic obstructive pulmonary disease (COPD) are presented in the form of an algorithm with 15 components, accompanied by detailed annotations. An algorithm is provided for <a href="Chronic Obstructive Pulmonary Disease">Chronic Obstructive Pulmonary Disease</a>; clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

# Clinical Highlights

- 1. Assess patients for symptoms and risk factors for COPD including asking about tobacco use/exposure at every visit. (Annotations #1, 2)
- 2. Establish diagnosis and severity of COPD through spirometry, pre-and post-bronchodilator and chest radiograph in addition to history and physical examination. (Annotation #3)
- 3. After establishing severity, assess patient needs for pharmacologic and non-pharmacologic treatment and provide appropriate pharmacotherapy as indicated. (Annotation #11)
- 4. Management of COPD should include an education plan suited to the patient's specific needs, encouragement of exercise, tobacco use cessation and other behavioral changes, and monitoring of immunization status. (Annotations #12, 13)
- 5. Patients should be regularly assessed for hypoxemia; appropriate oxygen therapy should be prescribed accordingly. (Annotation #14)
- 6. Physicians should discuss advance directives/health care directives and goals of care as early as possible. (Annotation #15)

# <u>Chronic Obstructive Pulmonary Disease Algorithm Annotations</u>

1. Symptoms of or Risk Factors for COPD

COPD may be indicated by the presence of one of the following symptoms:

- chronic cough (duration > 3 months) with or without sputum production
- dyspnea with or without wheezing

COPD should also be considered if the patient has one or more of the following risk factors:

 history of tobacco use or prolonged exposure to second-hand or environmental smoke

- asthma
- environmental exposure to occupational dust and chemicals (e.g. cadmium)
- alpha<sub>1</sub> antitrypsin deficiency
- chronic respiratory infections
- 2. Ask About Tobacco Use/Exposure at Every Visit

10-15% of long-term smokers develop COPD with accelerated rates of decline in forced expiratory volume in one second ( $FEV_1$ ). Tobacco cessation and oxygen therapy are the only interventions proven to prolong survival of patients with COPD. Reinforcement and follow-up for these patients is extremely important.

Advice and support from physicians and other health professionals are potentially powerful influences on tobacco cessation. According to the United States Surgeon General, tobacco use is one of the most important public health issues of our time. The National Cancer Institute, which is the primary federal agency for tobacco control, states that the keys to patient awareness and education about tobacco cessation in a clinical setting are:

ASK about tobacco use at every visit

ADVISE all users to stop

ASSESS users' willingness to make a quit attempt

ASSIST users' efforts to guit

ARRANGE follow up

For more information about tobacco cessation, please refer to the National guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) <u>Tobacco Use Prevention and Cessation for Adults and Mature Adolescents</u> guideline and the U.S. Department of Health and Human Services Clinical Practice Guideline, Treating Tobacco Use and Dependence.

Evidence supporting this recommendation is of classes: A, R

# 3. Establish Diagnosis of COPD

The diagnosis of COPD should be suspected based on the patient's medical history and physical examination, but requires spirometry to determine the degree of airflow limitation.

Signs/Symptoms for Which COPD May Be Suspected

- Wheezing, prolonged expiratory phase of respiration, rhonchi, and cough
- Dyspnea (exertional or at rest)
- Chronic sputum production

- Hyperinflation of the chest with increased anterior-posterior (A-P) diameter
- Use of accessory muscles of respiration
- Pursed-lip breathing
- Signs of cor pulmonale:
  - increased pulmonic component of the second heart sound (S2P)
  - neck vein distention
  - pedal edema
  - hepatomegaly

Note: Finger clubbing is not characteristic of COPD and should alert the clinician to another condition such as idiopathic pulmonary fibrosis (IPF), cystic fibrosis, lung cancer, or asbestosis.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines COPD as a disease characterized by airflow limitation that is not fully reversible, progressive, and related to exposure to tobacco or noxious particles or gases. See the National Guideline Clearinghouse (NGC) summary of GOLD's Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease.

Airflow obstruction is measured by spirometry and shows a reduced forced expiratory volume in one second (FEV $_1$ ) and FEV $_1$ /FVC (forced vital capacity) ratio. Measuring pre-and post-bronchodilator spirometry is important to identify those patients with partial reversibility of airflow obstruction. Partial reversibility is defined as improvement in airflow by 12% of baseline and 200 mL after administration of a bronchodilator.

## Spirometry

Spirometry is an established and important method of measuring lung function for the diagnosis and management of patients with COPD. It is recommended for patients at risk of COPD, particularly smokers greater than 45 years of age and for regular follow-up of patients with documented COPD.

Although peak flow meters should not be used to diagnose or monitor COPD, monitoring of peak expiratory flow (PEF) at home and at work can be used in certain situations to determine reversibility of and variability in airway obstruction.

Measurement of pre and post-bronchodilator  $FEV_1$  is important to distinguish COPD from asthma, as treatment and prognosis differ. Factors commonly used to distinguish COPD from asthma include: age of onset, smoking history, triggering factors, and occupational history.

Spirometry, interpretation strategies, selection of reference values and quality control should be performed in compliance with the Standards on Spirometry published by the American Thoracic Society (ATS). A list

of references for these standards can be found in Discussion Section #3 "Establish Diagnosis of COPD" of the original guideline document.

# Chest Radiograph

A chest radiograph is recommended at the time of diagnosis to exclude other causes. The chest radiograph in COPD is often normal but may show signs of hyperinflation, a flattened diaphragm, or bullae.

# • Bronchitis and Emphysema

The airflow obstruction in COPD may be due to chronic bronchitis or emphysema. Chronic bronchitis is defined as the presence of a chronic productive cough for 3 months in each of two successive years in a patient in whom other causes of chronic cough have been excluded.

Emphysema is defined as an abnormal permanent enlargement of the airspaces distal to the terminal bronchioles, accompanied by destruction of their walls, without obvious fibrosis. Radiographically, bullae may be visible on a chest computerized tomography scan or occasionally on a chest radiograph. Clinically, emphysema typically presents with a non-productive or minimally-productive cough and progressive dyspnea. Since both chronic bronchitis and emphysema result in airflow limitation, management goals are similar.

# Differential Diagnosis

In addition to asthma, possible differential diagnoses for COPD include bronchiectasis, cystic fibrosis, obliterative bronchiolitis, congestive heart failure, and upper airway lesions.

For more information on diagnosis and treatment of asthma, please refer to the National Guideline Clearinghouse (NGC) summary of the ICSI Diagnosis and Treatment of Asthma guideline.

#### 4. Acute Exacerbation?

Signs and symptoms of an acute exacerbation of COPD may include any of the following:

- Increased dyspnea
- Tachycardia
- Increased cough
- Increased sputum production
- Change in sputum color or character
- Use of accessory muscles
- Peripheral edema
- Development or increase in wheeze
- Loss of alertness
- Fatigue
- Fever

- Increased respiratory rate
- Decrease in FEV1 or peak expiratory flow
- Worsening of arterial blood gases (ABG) or pulse oximetry
- Chest tightness

Loss of alertness or a combination of two or more of the following new symptoms indicates a severe acute exacerbation:

- Dyspnea at rest
- Respiratory rate of > 25 breaths per minute
- Heart rate of > 110 beats per minute
- Use of accessory muscles

#### 5. Evaluation

When a patient with known COPD presents with a moderate to severe acute exacerbation, the following key elements of the history, physical examination, and laboratory/radiology evaluation should be considered:

# History

- Baseline respiratory status
- Present treatment regimen and recent medication use
- Signs of airway infection, e.g., fever and/or change in volume and/or color of sputum
- Duration of worsening symptoms
- Limitation of activities
- History of previous exacerbations
- Increased cough
- Decrease in exercise tolerance
- Chest tightness
- Change in alertness
- Other non-specific symptoms including malaise, sleeplessness, and fatigue
- Symptoms associated with comorbid acute and chronic conditions

# Physical Examination

- Tachycardia and/or hypotension
- Tachycardia and/or hypertension
- Increased respiratory rate
- Temperature
- Respiratory distress
- Accessory muscle use
- Increased pulmonary findings (e.g., wheezing, decreased air entry, etc.)
- Peripheral edema
- Alertness
- Acute comorbid conditions
- Measurement of pulse oximetry

# Laboratory/Radiology

- Chest x-ray (in patients with suspected respiratory infection)
- ABG (if O2 saturation < 88%, positive history of hypercapnia, questionable accuracy of oximetry, somnolence, or other evidence of impending respiratory failure [e.g., respiratory rate > 40 breaths per minute, etc.])
- Theophylline level (if theophylline is being utilized)
- White blood count (WBC) (in patients with suspected severe respiratory infection)

In patients with COPD exacerbation, there is not a good relationship with spirometry. For that reason, O2 saturation should be monitored.

There is little evidence regarding the contribution of additional laboratory testing or the usefulness of electrocardiography or echocardiography in an acute exacerbation of COPD. They may be a useful consideration in the presence of other comorbid conditions.

# 6. Treatment

## Bronchodilators

Albuterol is the preferred bronchodilator in the setting of an acute exacerbation of COPD because of its rapid onset of action. Serial administration is indicated until either relief of symptoms and improvement in signs of respiratory distress is achieved, or side effects of tachycardia and/or tremor develop. If clinical improvement does not occur before side effects develop, ipratropium bromide should be added to produce additive bronchodilation and allow the use of lower doses of albuterol, thus diminishing dose-dependent toxicity. No study has examined the benefit of using both agents concurrently or in combination form. Administration of either agent by metered dose inhaler (MDI) with a spacer is recommended, though the patient may be too dyspneic to retain a MDI puff effectively or severe coughing may prevent effective employment. In such cases, nebulization is necessary.

# Role of Levalbuterol (Xopenex®) in COPD

There are many theoretical advantages of levalbuterol over albuterol in the treatment of bronchospasm. Albuterol is a racemic combination of two isomers: the "R" isomer (levalbuterol) that is a potent bronchodilator, and the "S" isomer that has been shown in animal studies to counteract bronchodilation and can promote inflammation. Clinical studies in human subjects with acute bronchospasm have not consistently shown greater bronchodilation, or fewer side effects with levalbuterol. In individual patients with COPD and acute bronchospasm ipratropium is the next bronchodilator of choice. Levalbuterol may be an acceptable alternative as a trial agent, especially in patients whose bronchospasm worsens or shows no improvement on ipratropium.

# Steroids

Studies have shown benefits of systemic steroids in the outpatient management of COPD exacerbation. Doses of oral prednisone 30-60 mg per day should be used for 10 to 14 days. If longer durations are needed, consider a tapering schedule. There is no need to discontinue inhaled steroids while the patient is taking oral prednisone. In fact, the inhaled steroid may serve as a "systemic-steroid-sparing-agent" and the concomitant use may minimize the dose of systemic steroids needed to diminish airway inflammation.

#### **Antibiotics**

If the acute exacerbation of COPD is clearly caused by a virus, antibiotics are not necessary. In the presence of prolonged illness, with purulent sputum, an antibiotic is warranted. The choice of antibiotic is controversial, and needs to be tailored to the individual situation. "First-line agents," including amoxicillin, trimethoprim/sulfamethoxazole (TMP/SMX), doxycycline, and erythromycin, are often effective. If the incidence of resistant organisms is high enough in the community, the use of a "second-line agent" may be preferable. These second-line agents include second-generation cephalosporins, azithromycin, clarithromycin, and amoxicillin/clavulanate.

# Oxygen delivery

Oximetric evaluation of patients with COPD exacerbations is mandatory. Patients with O2 saturations of 80-90% on room air can be titrated with supplemental O2 to a saturation level of 90% with little concern of significant hypercarbia, unless such intervention results in somnolence. In such cases, or if the O2 saturation is less than 80% upon presentation, an ABG should be obtained. If the pH is less than 7.32, admission to the hospital should be arranged because of the risk of acute respiratory failure and the possible need for non-invasive ventilation. If outpatient management has been decided upon, the patient should be ambulated to determine what O2 flow is needed to maintain O2 saturations at 90% while walking.

# 7. Positive Response to Treatment?

The following criteria may be used as evidence of improvement in COPD exacerbation:

- Decrease in cough, sputum production, fever, or dyspnea
- Decrease in respiratory rate
- Decrease in heart rate
- Decrease in accessory muscle use
- Increase in function and endurance

# 8. Arrange for Follow-Up

A follow-up appointment between the primary care clinician and the patient should occur within 1-4 weeks to reassess management strategies and supplemental oxygen needs.

# 9. Admit to Hospital – Out of Guideline

The following may be indications to consider hospital admission for an acute exacerbation of COPD:

- Marked increase in intensity of symptoms, such as sudden development of resting dyspnea
- History of severe COPD, especially if mechanical ventilation was required
- Onset of new physical signs (e.g., cyanosis, peripheral edema)
- Failure of exacerbation to respond to initial outpatient medical management
- High risk comorbidities, pulmonary (e.g., pneumonia requiring hospitalization) or cardiac symptoms
- Increasing hypoxemia despite supplemental oxygen
- New or worsening CO2 retention or PH < 7.32
- Marked decrease in ability to ambulate, eat or sleep due to dyspnea
- History of prolonged, progressive symptoms
- Newly occurring arrhythmias
- Diagnostic uncertainty
- Older age
- Insufficient home support
- Decrease in alertness

# 10. Establish Severity of Stable COPD

The signs, symptoms, and air flow limitation in COPD vary with the severity of the disease. The severity of COPD may be categorized according to the following:

## Mild COPD

FEV<sub>1</sub> (% predicted): 80 or greater

Typical Symptoms and Signs:

- No abnormal signs
- Cough <u>+</u> sputum
- Little or no dyspnea

#### Moderate COPD

FEV<sub>1</sub> (% predicted): between 80 and 30

Typical Symptoms and Signs:

- Breathlessness (+ wheeze on moderate exertion)
- Cough (<u>+</u> sputum)
- Variable abnormal signs (general reduction in breath sounds, presence of wheezes)
- Hypoxemia may be present

#### Severe COPD

FEV<sub>1</sub> (% predicted): less than 30

Typical Symptoms and Signs:

- Dyspnea with any exertion or at rest
- Wheeze and cough often prominent
- Lung hyperinflation usual; cyanosis, peripheral edema and polycythemia in advanced disease
- Hypoxemia and hypercapnia are common

Table adapted from the National Heart, Lung and Blood Institute/World Health Organization (NHLBI/WHO) Global Initiative for Chronic Obstructive Lung Disease workshop summary.

# 11. Step-Care - Pharmacologic Approach for Managing Stable COPD

Each step in Table II represents an intervention that should be considered only if the previous course of action fails to improve symptoms of COPD. Step 1 is an intervention that is generally associated with mild COPD. Step 2 is associated with moderate COPD. Steps 3 and 4 are associated with severe COPD. While the intensity of pharmacological management generally increases with higher levels of severity, they are not necessarily directly correlated.

A table of estimated comparative doses for inhaled corticosteroids is attached in Annotation Appendix A "Estimated Comparative Daily Dosage for Inhaled Corticosteroids" in the original guideline document.

Albuterol and ipratropium are generally equipotent as bronchodilators, improving dyspnea and exercise tolerance. Salmeterol is a long-acting bronchodilator which is a suitable agent for scheduled administration. [Conclusion Grade II: Conclusion Grading Worksheet - Appendix A - Annotation #11 (Pharmacological Management) in the original guideline document.]

# Step-Care Pharmacologic Treatment of COPD

Step	Pharmaceutical Intervention	Dosing Information and Comments
1 Consider Step 2 if symptoms persist	Inhaled short-acting bronchodilator	Short-acting beta agonist (albuterol is preferred)  2-4 puffs, when necessary/as needed (PRN) (every 4-6 hours)
2	Continue when necessary/as needed (PRN)	

Step	Pharmaceutical Intervention	Dosing Information and Comments
Consider Step 3 if symptoms persist	inhaled short-acting bronchodilator PLUS scheduled dosing of one of the following:	
	Salmeterol* (Serevent® Discus) Formoterol* (Foradil®) Albuterol (Proventil®, Ventolin®) Ipratropium (Atrovent®) Albuterol + Ipratropium (Combivent®) Levalbuterol	1 puff twice a day (BID) 1 puff (12 mcg) BID 2-4 puffs, 4 times a day (QID) 2-4 puffs QID 2-4 puffs QID 0.63-1.25 mg every 6-8 hours via nebulizer
3 Consider Step 4 if symptoms persist	Continue therapy in Step 2 and perform corticosteroid trial  Assess symptoms before and after trial period, especially cough and sputum production. Also measure post-bronchodilator FEV <sub>1</sub> ± 6-minute walk before and after trial	Prednisone PO 30-40 mg/day for 2-4 weeks or inhaled corticosteroid in a dose 1600 micrograms beclomethasone/day or dose equivalent of another inhaled steroid for 6-12 weeks  Approximately 15% of patients who undergo a corticosteroid trial will have improved symptoms and post-bronchodilator FEV <sub>1</sub>

 $<sup>^{\</sup>star}$  A long-acting beta agonist is the preferred scheduled bronchodilator. Refer to the discussion section in the original guideline document for more information.

Step 4: Response After Step 3?		
Positive	Negative	
Positive Response: greater than or equal to 15% improvement in post-bronchodilator FEV1, symptoms <u>+</u> improvement in 6-minute walk.	Negative Response: less than 15 % improvement in post-bronchodilator FEV1 or no improvement in symptoms +/- 6-minute walk.	
Pharmaceutical Intervention: Taper off or discontinue oral corticosteroids and prescribe or continue inhaled corticosteroids.	Pharmaceutical Intervention: Discontinue corticosteroids and consider theophylline as adjunctive	

Step 4: Response After Step 3?			
Positive	Negative		
Dosing Information: A comparison of dosages of inhaled corticosteroids is attached in Annotation Appendix A of the original guideline document.	therapy with inhaled bronchodilators (beta2-agonists and/or ipratropium). If no benefit from theophylline, discontinue.  Dosing Information: Therapeutic range of theophylline at a steady state has conventionally been considered to be 10-20 micrograms/mL, but lower serum concentrations of 5-15 micrograms/mL provide similar efficacy with a lower incidence of adverse effects.  Theophylline has a narrow therapeutic index with potentially significant adverse effects and drug interactions that must be carefully considered and closely monitored during therapy.		

# Methods of Inhaled Drug Delivery

- Metered Dose Inhaler (MDI) with spacer. Some studies support the use
  of spacers to obtain effective metered dose inhaler drug delivery. The
  increased distance slows the velocity of the fine particles, increasing
  their chances of reaching the bronchial tree. It is of utmost importance
  to train and re-train patients, nurses, physicians, and pharmacists in
  the proper inhaler technique for optimal drug delivery. Evidence of the
  effectiveness of one spacer over another is variable and controversial.
- Dry Powder Inhaler (DPI). Dry powder inhalers are an alternative to metered dose inhalers that are strongly supported by study data. Dry powder inhalers deliver drugs in dry-powder form without the use of propellants. In addition, dry powder inhalers are breath-activated, eliminating the need to synchronize inhalation with actuation.
- Nebulizers. Aerosol therapy via nebulizer is generally considered expensive, inconvenient, and inefficient. Nebulizer therapy should be considered a second choice when compared with other modes of aerosol delivery, e.g., metered dose inhalers and dry powder inhalers. Aerosol therapy via nebulizer should also be considered when patients are unable to perform a metered dose inhaler or dry powder inhaler maneuver consistently or effectively.

# Theophylline

Theophylline has a narrow therapeutic index with potentially significant adverse effects and drug interactions that must be carefully considered and closely monitored for during therapy.

Evidence supporting these recommendations are of the following classes:

- Albuterol and ipratropium: A, M
- Combination albuterol and ipratropium: A
- Long-acting beta agonists: A
- Systemic corticosteroid trials: R
- Inhaled corticosteroids: A, B, M
- 12. Other Pharmacologic Treatment

#### **Antibiotics**

The routine use of antibiotics is not recommended except for treatment of bacterial exacerbations of COPD.

#### **Antitussives**

Regular use of antitussives is not recommended in COPD since cough can have a significant protective effect.

# **Antiviral Agents**

Treatments other than vaccination are available to treat influenza, but are not a substitute for vaccination unless it is contraindicated. Amantadine (Symmetrel®) and rimantadine (Flumadine®) are indicated for symptomatic treatment and prophylaxis of influenza A which is more prevalent and more severe than influenza B. If started within the first 48 hours of symptom onset, amantadine and rimantadine may reduce the duration and symptoms by 50%.

Zanamivir (Relenza®) and oseltamivir (Tamiflu®) are also available. Zanamivir must be inhaled whereas oseltamivir is available orally. Zanamivir and oseltamivir may be considered for treatment if there is an outbreak of influenza B. These medications are, however, very costly relative to their benefits.

Because of a single case report of respiratory distress associated with zanamivir, published in a letter to the New England Journal of Medicine, caution should be exercised in the use of zanamivir in patients with COPD.

Refer to the original guideline document for information on costs of antiviral agents.

## Leukotriene Modifiers

This drug class has not been adequately tested in COPD patients and cannot be recommended.

# Mucolytics

There may be isolated circumstances (especially in the presence of copious, thick secretions) in which an individual with COPD might benefit from a mucolytic or mucoactive agent. In general, however, drugs from this class have not been shown to be effective and are not recommended as treatment for COPD.

Evidence supporting this recommendation is of classes: A, C, R

Oral Beta Agonists

Inhaled bronchodilator therapy is preferred.

Vaccines

Immunization with influenza and pneumococcal vaccines is recommended to reduce infectious complications involving the respiratory tract. Influenza vaccine should be provided on an annual basis because of new antigens and waning immunity from the previous year. Pneumovaccination should be repeated once in high risk patients, including those with COPD, if at least 5 years have passed since the previous vaccination. For more information on vaccination protocols for persons with chronic lung disease, refer to the ICSI Immunizations guideline.

Evidence supporting this recommendation is of class: R

- 13. Non-Pharmacologic Treatment All Levels of Severity
  - Encourage exercise
  - Education. Refer to the original guideline document for presentation of a Patient Education Model. The model presents core learning needs and objectives along with some examples of tools to assist individual clinicians in designing a patient education plan. This model is based on the Transtheoretical Change Model (Prochaska Model), which emphasizes recognition of patients' stages of readiness to incorporate educational messages into long-term behavior change.

Evidence supporting this recommendation is of classes: A, C, D, M, R,  $\rm X$ 

14. Assess for Hypoxemia and Hypercapnia and Treat if Indicated

Initial Assessment for Hypoxemia and/or Hypercapnia

The evaluation of gas exchange status by arterial blood gas (ABG) measurement is recommended for initiation of oxygen therapy as well as to determine PCO<sub>2</sub> and acid-base status. Assessment for long-term oxygen needs by arterial blood gas analysis should be considered for stable outpatients with:

1. Severe airflow obstruction

- 2. Symptomatic dyspnea with polycythemia, pulmonary hypertension (by electrocardiogram or echo), or altered mental status
- 3. Problematic heart failure
- 4. Severe symptoms out of proportion to the degree of airway obstruction

Pulse oximetry cannot determine acid-base status and is not considered sufficiently accurate to replace arterial blood gas measurement in an initial assessment. Arterial blood gas measurement can be used to confirm the accuracy of pulse oximetry at rest and, perhaps more importantly, with exercise when oximetry is less reliable.

# Nocturnal Hypoxia

During sleep, even in individuals without COPD, minute ventilation decreases. In patients with COPD whose  $O_2$  saturation is already low or borderline, this hypoventilation results in hypoxia, which can exacerbate or precipitate pulmonary hypertension. Sleep disruption from hypoxia or sleep apnea can induce daytime hypersomnolence and may worsen symptoms of COPD.

Risk Factors for Hypoxia During Sleep

- Severe COPD, especially with resting oxygen saturation less than 88% or exercise-induced hypoxia
- Evidence of cor pulmonale
- Daytime hypersomnolence in the absence of sleep deprivation
- Polycythemia

## Screening for Nocturnal Hypoxia

Screening for nocturnal hypoxia can be done easily and inexpensively with overnight pulse oximetry in the home. The oximeter is returned to the clinic, where the overnight oximetry and heart rate data are downloaded. If a significant portion of the night's data indicates oxygen saturations below 88%, supplemental oxygen can be provided empirically at 1-2 L/min. Home oximetry can be repeated at that level to verify correction of hypoxia.

The patient should be referred to a sleep specialist to rule out sleep-related disordered breathing if additional abnormalities are present.

Evidence supporting these recommendations is of classes: A, C, D

# Hypercapnia

In an ambulatory, stable patient with COPD, assessment for hypercapnia by arterial blood gases should be considered in the following circumstances:

- Clinical suspicion of hypercapnia (asterixis, headache, hypersomnolence, altered mental status)
- $FEV_1 < 1.0$
- Upon initiation of oxygen

- Morbid obesity
- Excessive daytime somnolence
- Problematic right heart failure/cor pulmonale
- Severe airflow obstruction

Carbon dioxide ( $CO_2$ ) retention may pose a threat in patients with impaired  $CO_2$  ventilatory drive. Careful titration of supplemental oxygen should be performed in these patients. A pH drop along with a rise in  $PaCO_2$  with initiation of oxygen therapy or an increase in inspired oxygen concentration is usually well tolerated in the ambulatory stable patient with COPD. If hypercapnia results in a decrease in mental status, the patient may need admission to a hospital for more intensive respiratory care and monitoring.

In the unstable patient or patients with resting hypercapnia, initiation of supplemental oxygen should be titrated upward, as there is a small risk of worsening CO<sub>2</sub> retention. Reassessment by arterial blood gases (ABG) and clinical status looking for signs/symptoms of hypercapnia is suggested 30 minutes after initiation of oxygen.

These recommendations are further clarified in the ICSI Diagnosis and Treatment of Obstructive Sleep Apnea Hypopnea Syndrome guideline.

# Oxygen Therapy

## Important points:

- Long-term oxygen therapy (>15 hours per day) improves survival and quality of life in hypoxemic patients with COPD.
- Arterial blood gas measurement is recommended for initiation of oxygen therapy as well as to determine PCO<sub>2</sub> and acid-base status.
- Pulse oximetry is a good method for monitoring oxygen saturation and can be used in adjusting the oxygen flow setting.
- Indications for long-term oxygen therapy have been adopted by Medicare as reimbursement criteria. (Annotation Appendix B in the original guideline document contains a summary of Medicare Oxygen Coverage)
- Patients considered for long-term therapy may benefit from assessment by a pulmonologist.
- Supplemental long-term oxygen therapy should be provided at a flow rate sufficient to produce a resting  $P_aO_2$  of >55 mm Hg, or  $S_aO_2$  greater than 89%.
- Titrate liter-flow to goal at rest: add 1 L/min during exercise or sleep or titrate during exercise to goal of S<sub>a</sub>O<sub>2</sub> greater than 89%. Titrate sleep liter-flow to 8 hour sleep of S<sub>a</sub>O<sub>2</sub> greater than 89%.
- Consider referral for sleep evaluation if patient experiences cyclic desaturation during sleep but is normoxemic at rest.
- Recheck S<sub>a</sub>O<sub>2</sub>or P<sub>a</sub>O<sub>2</sub> in 1-3 months if hypoxia developed during an acute exacerbation. Rechecks should be performed annually if hypoxia is discovered in an outpatient with stable COPD.

Evidence supporting this recommendation is of classes: C, D

#### COPD and Air Travel

Airline travel is safe for most patients with COPD. Hypoxemic patients should be evaluated clinically, and a decision should be made regarding oxygen requirements. Patients with COPD receiving continuous oxygen at home will require supplementation during flight. A doctor's order is required for patients who need supplemental oxygen during air travel. Special arrangements with oxygen or equipment suppliers and the airline must be made at least 48 hours prior to departure.

Use of supplemental O2 for patients with COPD and not currently on supplemental O2

Regression equations have been validated which predict pO2 at usual atmospheric pressures in aircraft. These predict that patients with FEV1 <80% and pO2 <80 will have in-flight pO2 <55% and therefore should be prescribed supplemental O2 at 2 L/M. Patients with underlying cardiovascular or cerebrovascular disease should be prescribed O2 if their FEV1 and pO2 are even higher.

# 15. Follow-Up

Schedule Regular Follow-Up Visits

Follow-up visits should be jointly established between primary care physicians and pulmonary specialists, and should be tailored to the learning stage and comorbidities of individual patients.

The exact frequency of clinician visits is a matter of clinical judgment; however, the following may serve as a general guide.

Mild Severity: Follow-up 6-12 months

Moderate Severity: Follow-up 3 months

Severe: Follow-up 1-2 months or more frequently as needed

Consider Referral to Pulmonary Specialist

Obtaining the opinion of a pulmonary specialist may be beneficial at any stage of the disease. Referral may be indicated to confirm the diagnosis, facilitate tobacco cessation, and optimize appropriate treatment.

Referral may be indicated:

- For patients under age 40 years or with a family history of emphysema or alpha<sub>1</sub>-antitrypsin deficiency in order to identify the deficiency, treat and screen family members.
- To confirm diagnosis, rule out other etiologies, symptoms, complexities and to optimize treatment.

- If symptoms are not consistent with the lung function deficit as measured by pulmonary function tests.
- For patient with frequent infections and/or possible bronchiectasis.
- For assessment of long-term treatment with oral corticosteroids if results of steroid trial are unclear.
- To identify and assess patients for possible lung volume reduction surgery or lung transplantation.
- For patients with rapid decline in FEV<sub>1</sub> to optimize early intervention.
- For patients with smoking history of less than 10 pack years to exclude/confirm diagnosis.
- For patients with frequent exacerbations.

# Consider Referral to Pulmonary Rehabilitation Program

The primary goal of pulmonary rehabilitation is to decrease respiratory symptoms and improve quality of life. Pulmonary rehabilitation, with a multidisciplinary approach including education and exercise training, may be considered for COPD patients who have functional limitations that affect their quality of life, have maximized on standard medical therapy, and are not limited by other serious or unstable medical conditions. For willing patients who are able to learn about their disease and are motivated to participate in a comprehensive rehabilitation program, selecting a program that emphasizes regular in-home exercise verified by an exercise log is strongly recommended. Long-term benefits from programs after completion have not been demonstrated except for home-based exercise programs. A summary of structures and services in pulmonary rehabilitation is attached in Annotation Appendix C "Summary of Structure and Services - Pulmonary Rehabilitation Program" of the original guideline document.

Discuss Health Care Directives (Advance Directives) Or Living Will and Durable Power of Attorney for Health Care

Many patients have an interest in discussing living wills but their wishes tend to be passive and unspoken.

Physicians are encouraged to initiate and facilitate conversations about living wills with all COPD patients at routine outpatient visits.

In patients with severe disease, it is also helpful to discuss specific treatment preferences and the goals of care. Treatment preferences may include: home care only, hospitalization for comfort care, initiation full life support if there is a reasonable chance for recovery to functional independence, or continuation of indefinite life support in a chronic nursing facility.

- Objectives of Discussion
  - 1. To encourage physicians to discuss health care directives with COPD patients
  - 2. To give patients control over their end-of-life care
  - To ensure that patients' wishes will be carried out at the end of their life
  - 4. To increase the number of COPD patients who have written health care directives

- 5. To increase the number of patients with severe COPD who have discussed specific treatment preferences and goals of care
- 6. To name a Durable Power of Attorney for Health Care or an appropriate surrogate decision maker
- Plan for Discussion
  - For the patient with moderate to severe COPD, at a routine office visit ask the question, "Do you have a living will?"

Action: If yes, ask what it consists of (especially whether there is a designation of durable power of attorney and who that person is) and request that a copy be placed in the patient's medical record.

Action: If no, offer the patient written information on health care directives, encourage them to fill out a health care directive including designation of power of attorney for health care and offer to discuss any questions at the next office visit.

• For the patient with severe COPD, at a routine office visit ask the question, "What are your treatment preferences in regards to hospitalization, life support (including cardiopulmonary resuscitation (CPR), endotracheal intubation and non-invasive ventilation), and end-of-life care?"

Action: Encourage the patient to discuss these treatment preferences with family or health care surrogate and record them in a health care directive.

Action: Document the patient's treatment preferences in the patient's medical record and request that a copy of the health care directive be placed in the patient's medical record.

For more information on living wills, please refer to the original guideline document.

Evidence supporting this recommendation is of classes: D, R

# Definitions:

#### Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or

because of doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusions because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade IV: The support for the conclusion consists solely of the statements of informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

Grade Not Assignable: There is no evidence that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

• Randomized, controlled trial

Class B:

Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report
- B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis

Cost-effectiveness analysis

## Class R:

- Consensus statement
- Consensus report
- Narrative review

## Class X:

Medical opinion

## CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for <u>Chronic Obstructive</u> Pulmonary Disease.

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## POTENTIAL BENEFITS

Accurate diagnosis, evaluation of severity, and effective management of patients presenting with symptoms of stable chronic obstructive pulmonary disease (COPD)

# POTENTI AL HARMS

# Adverse effects of medication

- Theophylline may cause gastrointestinal irritation (nausea, dyspepsia, and gastroesophageal reflux disease [GERD]), irritability, tremor, and sleep disturbance. Theophylline has a narrow therapeutic index with potentially significant adverse effects and drug interactions that must be carefully considered and closely monitored for during therapy.
- Tremor can develop with high doses of albuterol and salmeterol
- Steroid side effects, especially with oral corticosteroid use

# CONTRAINDICATIONS

## **CONTRAINDICATIONS**

Relative Contraindications for Participation in Pulmonary Rehabilitation

- Patients with conditions that might interfere with the patient undergoing a rehabilitation program (e.g., coronary artery disease, cognitive impairment interfering with learning, severe psychiatric disturbances)
- Patients with conditions that might place the patient at risk during exercise training; many patients with chronic obstructive pulmonary disease (COPD) are older with a history of cigarette smoking and are at risk for heart disease. Cardiac and pulmonary stress testing should be routinely performed to exclude silent cardiac disease and assure safety during exercise training.

# QUALIFYING STATEMENTS

#### **OUALIFYING STATEMENTS**

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

# IMPLEMENTATION OF THE GUIDELINE

# DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline

recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

End of Life Care Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

# IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Chronic obstructive pulmonary disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Dec. 67 p. [113 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## DATE RELEASED

2001 Dec (revised 2003 Dec)

## GUI DELI NE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

# GUI DELI NE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic,

North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health &: Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, St. Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: <a href="mailto:icsi.info@icsi.org">icsi.info@icsi.org</a>; Web site: <a href="mailto:www.icsi.org">www.icsi.org</a>.

# SOURCE(S) OF FUNDING

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne, and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

#### **GUIDELINE COMMITTEE**

Respiratory Steering Committee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: James Mickman, MD (Work Group Leader) (HealthPartners Medical Group) (Pulmonary & Critical Care Medicine); Jeff Rabatin, MD (Mayo Clinic) (Pulmonary & Critical Care Medicine); Tom Dashiell, MD (HealthEast Clinics) (Internal Medicine); James Eelkema, MD (Quello Clinic) (Family practice); Allen Horn, MD (CentraCare Clinic) (Family Practice); Suzanne Tschida, PharmD (HealthPartners Medical Group) (Pharmacy); Scott Copeman, RRT, RCP (Mayo Clinic) (Respiratory Therapy); Jeff Norton, CRT, RCP (Fairview Health Services) (Respiratory Therapy); Catherine Youngman, RN (HealthPartners Medical Group) (Nursing and Health Education); Leslie Schneider, RN (Park Nicollet Health Services) (Nursing and Health Education); Nancy Jaeckels (Institute for Clinical Systems Improvement) (Evidence Analyst); Jenelle Meyer, RN (Institute for Clinical Systems Improvement) (Facilitator)

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, the Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Chronic obstructive pulmonary disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Jan. 63 p.

The next scheduled revision will occur within 18 months.

#### GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Institute for Clinical Systems Improvement</u> (ICSI) Web site.

Print copies: Available from the Institute for Clinical Systems Improvement, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: <a href="www.icsi.org">www.icsi.org</a>; email: <a href="icsi.info@icsi.org">icsi.info@icsi.org</a>.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Chronic obstructive pulmonary disease. In: ICSI pocket guidelines. April 2003 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2003 Mar. p.198-204.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: <a href="www.icsi.org">www.icsi.org</a>; e-mail: <a href="icsi.info@icsi.org">icsi.info@icsi.org</a>.

#### PATIENT RESOURCES

None available

# NGC STATUS

This NGC summary was completed by ECRI on August 26, 2002. The information was verified by the guideline developer on September 23, 2002. This summary was updated by ECRI on July 12, 2004.

# COPYRIGHT STATEMENT

This NGC summary (abstracted Institute for Clinical Systems Improvement [ICSI] Guideline) is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

The abstracted ICSI Guidelines contained in this Web site may be downloaded by any individual or organization. If the abstracted ICSI Guidelines are downloaded by an individual, the individual may not distribute copies to third parties.

If the abstracted ICSI Guidelines are downloaded by an organization, copies may be distributed to the organization's employees but may not be distributed outside of the organization without the prior written consent of the Institute for Clinical Systems Improvement, Inc.

All other copyright rights in the abstracted ICSI Guidelines are reserved by the Institute for Clinical Systems Improvement, Inc. The Institute for Clinical Systems Improvement, Inc. assumes no liability for any adaptations or revisions or modifications made to the abstracts of the ICSI Guidelines.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/1/2004



